



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	17E1.20
True Name	Hemorrhagic Enteritis Vaccine, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	December 18, 2017

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Hemorrhagic Enteritis Vaccine, Live Virus
Study Purpose	Demonstrate efficacy against virulent hemorrhagic enteritis virus
Product Administration	One dose, administered through drinking water
Study Animals	Five week old turkeys divided into 3 groups Group 1: vaccinated with product and challenged Group 2: sham vaccinated and challenged (positive control) Group 3: sham vaccinated, non-challenged (negative control)
Challenge Description	Domermuth strain of hemorrhagic enteritis virus administered at 3 weeks post vaccination
Interval observed after challenge	Observed daily for 4 days and then evaluated for internal changes (lesions) specific to hemorrhagic enteritis virus infection.
Results	Vaccinates and controls were evaluated in terms of hemorrhagic enteritis clinical signs and/or grossly observable lesions. No birds showed clinical signs after challenge. Birds with observable lesions: Group 1: 2/32 Group 2: 21/22 Group 3: 0/22 Raw data on attached page
USDA Approval Date	

Raw data shown below for birds classified as positive. All other birds normal

Group/Bird	Enlarged and/or marbled spleen	Hyperemic or hemorrhagic intestine
Group 1/340	x	
Group 1/357	x	
Group 2/303	x	
Group 2/305	x	
Group 2/310	x	x
Group 2/316	x	
Group 2/321	x	x
Group 2/322	x	x
Group 2/325	x	x
Group 2/327	x	
Group 2/331	x	x
Group 2/332	x	
Group 2/334	x	
Group 2/337	x	x
Group 2/338	x	
Group 2/353	x	
Group 2/354	x	x
Group 2/358	x	x
Group 2/361	x	
Group 2/362	x	x
Group 2/367	x	
Group 2/372	x	x
Group 2/376	x	x

Study Type	Safety							
Pertaining to	ALL							
Study Purpose	Field safety							
Product Administration	Single dose by drinking water route.							
Study Animals	Commercial turkeys at 28 to 36 days of age, 4 independent study sites.							
Challenge Description	Not applicable							
Interval observed after challenge	Turkeys were observed for mortality and adverse reactions up to 3 weeks post vaccination.							
Results	Site		Number of Turkeys		21 Day Mortality		% Mortality	
		Vaccinates	Controls	Vaccinates	Controls	Vaccinates	Controls	
	1	25,200	20,800	727	907	2.9	4.4	
	2	25,658	24,600	657	716	2.6	2.9	
	3	38,759	27,082	845	332	2.2	1.2	
	4	20,573	20,638	86	119	0.4	0.6	
No adverse reactions attributable to the vaccine were recorded.								
USDA Approval Date	October 12, 2017							